**Institutional Biosafety and Chemical Safety Committee**



**Modification/Annual Review Form**

 **for Recombinant or Synthetic Nucleic Acid Experiments**

**Please submit this form for annual review or to request changes in personnel or project prior to the changes. Send completed MS Word file to** **research@etsu.edu****. When completing the form using the Mac version of Word, place the cursor in front of the box and tap the space bar. Please return original, signed affirmation form (Section 13 & 14) to: Vice Provost for Research, Box 70565. The forms have been revised; please review the instructions prior to completion of the forms.**

**Please indicate all changes by highlighting in yellow the corresponding text and information (hint: use ).**

**East Tennessee State University requires that all recombinant or synthetic nucleic acid work conducted at or supported by this University be registered with and approved by the Institutional Biosafety and Chemical Safety Committee.**

**Please consult the ETSU General Policies for the Use of Recombinant or Synthetic Nucleic Acid Molecules and *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (***[***http://www4.od.nih.gov/oba***](http://www4.od.nih.gov/oba)**) for information needed to complete this form.**

Source of NA (i.e., organism, clone bank, species, etc. and literature citation if appropriate)

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| Biosafety Registration Number that was assigned to this project -- **REQUIRED**:  |
| Principal/Responsible Investigator:  | Phone number:  |
| E-mail address:  | Building & Room #:  |
| Department Name and Box #:  | Fax #:  |
| Location of Experiments (building & room):  | Sponsor:  |
| Project Title:  |
| Do you have a Materials Transfer Agreement? [ ]  Yes [ ]  No |

[ ] No changes since last submission

* If containment level requires BSL-2 conditions, provide location and most recent date of certificate.

 (See sections 8a & 8b)

* Complete section 13 and route original to the Vice Provost for Research, Box 70565

[ ] Changes in personnel only

* If containment level requires BSL-2 conditions, provide location and most recent date of certificate.

 (See sections 8a & 8b)

* Complete sections 13 & 14 and route signed original documents to the Vice Provost for Research, Box 70565

[ ] Changes in project

* Complete all sections of the Annual Review Form (sections 1-14)

Route completed original affirmation form to the Vice Provost for Research, Box 70565

**NON-EXEMPT RECOMBINANT OR SYNTHETIC NUCLEIC ACID REGISTRATION**

1. Please check any of the following that pertain to this experiment. Please note: this category may require additional information to be submitted with the registration, contact the Chair of the Recombinant or Synthetic Nucleic Acid Subcommittee of the ETSU Biosafety and Chemical Safety Committee for further information.

[ ]  Expression of toxic products

[ ]  Use of transgenic animals

[ ]  Use of transgenic plants

[ ]  Experiment will involve more than 10 liters of culture

2. Check the category (a, b, or c) of Recombinant or Synthetic Nucleic Acid experiments you wish to perform (check all that apply).

[ ]  a. Experiments that require committee notice at the time of initiation (ETSU General Policies Section 2 and *NIH Guidelines Section III-E*). Please include abrief description of the experimental plan and indicate the relevant section of the *NIH Guidelines*.

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[ ]  b. Experiments that require approval by this committee before initiation (ETSU General Policies Section 3 and *NIH Guidelines Section III-D*).

* Experiments using an adenovirus or retrovirus vector
* Experiments using human or animal pathogens (Risk Groups 2, 3, or 4 ) as host-vector systems
* Experiments in which DNA from human or animal pathogens is cloned in nonpathogenic prokaryotic or lower eukaryotic host-vector systems
* Experiments involving the use of infectious animal or plant viruses or defective viruses in the presence of helper virus in a tissue culture system
* Experiments involving whole animals or plants

[ ]  c. Experiments that require specific approval by both NIH and this committee before initiation (ETSU General Policies Sections 4, 5, 6 and *NIH Guidelines Section III-A, B,* C). Please note: this category requires additional information to be submitted with the registration, contact the Chair of the Recombinant or Synthetic Nucleic Acid Subcommittee of the ETSU Biosafety and Chemical Safety Committee for further information.

* Deliberate cloning of genes for highly toxic products
* Deliberate release of recombinant organisms to the environment
* Transfer of drug-resistance if such transfer might compromise use of drug therapeutically
* Transfer of Recombinant or Synthetic Nucleic Acid to humans including gene therapy

For work in all three categories above, please describe the following areas in detail:

3. Source of DNA(s) or Synthetic Nucleic Acids (i.e., organism, clone bank, species, etc., and literature citation
if appropriate).

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4. Nature if Inserted Sequence (genomic cDNA, PCP products etc.)

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5. Specific Host(s)

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6. Specific Vector(s) (e.g. source of vector, supplier and type)

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7. List the Risk Group for your source or vector (*Defined in Appendix B of the NIH Guideline)*

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8. List the Containment Level (*Defined in Appendix G of the N IH Guidelines*): Biosafety Level (BL)

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| BL- |

If BL-2, give a) the location and b) the date of certification.

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9. Will the studies include deliberate attempts to obtain expression of a foreign gene (a gene originally exogenous to the host-vector system used)?

[ ]  Yes [ ]  No

If yes, what protein will be produced?

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10. Does this research protocol require either ETSU IRB or ETSU Animal Care Committee approval? If yes, which?

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11. List the names of all personnel participating in this study and have them initial by their names to indicate that they have read and understand the nature of these experiments and that they can safely and properly handle the material described (add more rows if necessary).

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| **NAME** | **TITLE** |
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12. Please describe progress of ongoing studies and list any proposed changes. Please limit to one page.

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13. **Principal Investigator Affirmation:**

I acknowledge my responsibility for the conduct of this research in accordance with Section IV-B-7 of the *NIH Guidelines*. I accept responsibility for the safe conduct of work with this material and have received appropriate training on the hazards and the level of containment required to perform this research safely. I will report to the Biosafety and Chemical Safety Committee any accident or incident that results in a potentially toxic exposure to personnel or any incident releasing Recombinant or Synthetic Nucleic Acid or other potentially hazardous materials into the environment.

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| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Principal Investigator (signature) | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Chairperson, Biosafety and Chemical Safety Committee (signature) | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date |

14. **Project Personnel AFFIRMATION: a separate document (see website)**